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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,997	06/21/2007	Eric James Wall	CHM-022M	8939
38155	7590	02/12/2009	EXAMINER	
HASSE & NESBITT LLC 8837 CHAPEL SQUARE DRIVE SUITE C CINCINNATI, OH 45249			PRICE, NATHAN R	
			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/597,997	Applicant(s) WALL ET AL.	
	Examiner NATHAN R. PRICE	Art Unit 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/08/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, drawn to a device comprising a separable base.

Group II, claim(s) 12-15, drawn to a device comprising two needles and two reservoirs.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I, a separable base, is not shared by Group II. The special technical feature of Group II, two needles and two reservoirs, is not shared by Group I.

Lack of unity of invention may be directly evident "a priori," that is, before considering the claims in relation to any prior art, or may only become apparent "a posteriori," that is, after taking the prior art into consideration. For example, independent claims to A + X, A + Y, X + Y can be said to lack unity a priori as there is no subject matter common to all claims. In the case of independent claims to A + X and A + Y, unity of invention is present a priori as A is common to both claims. However, if it can be established that A is known, there is lack of unity a posteriori, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.

2. During a telephone conversation with Daniel Nesbitt on January 27, 2008 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Objections***

4. Claims 3, 6, 8, and 11 are objected to because of the following informalities:

5. In claim 3, “comprises **a** adhesive” should be amended to “comprises **an** adhesive.”

6. In claim 6, “wherein **the engaging member** has a first position” lacks antecedent basis. It is recommended to amend to “wherein **the at least one engagement member** has a first position.”

7. In claim 8, the limitation “the latch” lacks antecedent basis since claim 8 is dependent on claim 6. It is recommended to either amend claim 8 to be dependent on claim 7, where “a latch” is originally recited, or to amend to “a latch”.

8. In claim 11, the limitation “the engaging member” lacks antecedent basis. For the purposes of examination, it is assumed that “the engaging member” in claim 11 refers to the same “at least one engaging member” recited in claims 6-8. Claim 11, however, does not depend on claims 6-8. It is recommended to amend dependency of claims 9-11 or define the element earlier in the claim.

9. Appropriate correction is required.

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***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over McConnell-Montalvo et al. (US 6939330) in view of Woehr et al. (US 20030144627) and Hunn et al. (US 20040158207).

12. Regarding claims 1-5, as best understood, McConnell-Montalvo et al. discloses an improved injection device for self-administering vaccine injections painlessly to a patient, comprising: a housing 70 (fig. 6) having a base portion (comprising elements 98 and widened distal end of housing 70, fig. 6 and 8); a needle 18 (fig. 8) positioned within the housing, the needle having an injection end (sharp distal end, fig. 8), and being configured for extension to a position wherein the injection end extends through and beyond the base portion (see fig. 9); a reservoir for the vaccine (syringe barrel 10, fig. 8); and a means for liquid communication between the reservoir and the injection needle (needle 18 and reservoir 10 are connected in fluid communication, see fig. 8); a separable base (comprising elements 98, 102, and 106; fig. 8) associated with the base portion, a means for separably affixing the separable base with the base portion (interface between 100, 102) which is a mechanical securement (see fig. 8-9); the separable base is capable of being re-affixed to the base portion after separation (elements 102 are separated from the base during movement from position in fig. 8 to

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position in fig. 9, and in fig. 9 are reaffixed to the base at the top of space 100); **except** for the needle having an outside diameter greater than 0.20 mm and less than about 0.38 mm, an adhesive on a skin-facing surface thereof, an adhesive flap extending from a periphery of the separable base, the flap having an adhesive on a skin-facing surface thereof, whereby the flap provides securement of the separable base to the skin of the patient.

13. However, Woehr et al. teaches injection needles with diameters in this range (see table 1, page 5, which specifically mentions needle outer diameters of .3 mm, .33mm, and .35 mm). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the McConnell-Montalvo et al. apparatus such that the injection needle has an outside diameter greater than .10mm and less than about .38 mm, as taught by Woehr et al., for the purpose of providing a needle of sufficiently sized diameter to require an appropriate application of strength for use (par. 0079, table 1).

14. Furthermore, Hunn et al. teaches an adhesive 2 (fig. 9; par. 0064) on a skin-facing surface comprising a flap that extends around the periphery of the base (see fig. 9). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the McConnell-Montalvo et al. apparatus such that it comprises an adhesive on a skin-facing surface thereof, an adhesive flap extending from a periphery of the separable base, the flap having an adhesive on a skin-facing surface thereof, whereby the flap provides securement of the separable

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base to the skin of the patient, as taught by Hunn et al., for the purpose of holding the apparatus in place at an injection site (par. 0064).

15. Regarding claims 6-11, as best understood, McConnell-Montalvo et al. discloses the apparatus as claimed except for the means for separably affixing comprises engagements in the opposed surface of the separable base; and engaging members extending from the base portion of the housing; wherein the engaging members have a first position associated with the engagement wherein the removable base is secured to the housing, and a second position associated with the engagement wherein the removable base is not secured to the housing; the removable base has a slot in the opposed surface, wherein the engaging member has a latch whereby the latch engages the slot in its first position, thereby securing the separable base to the housing, and wherein the engaging member can be biased to the second position wherein the latch is not engaged with the slot, thereby unsecuring the separable base to the housing; the engaging member has a button affixed thereto configured to accept a biasing force from outside the housing (preferably, through an opening within the housing), which biases the latch of the engaging member to its second, unsecured position; a means for retracting the injection needle whereby the injection end of the needle is retracted from its extended position to a position within the housing; the retracting means comprises a means for moving a needle insertion securement from a first position wherein the needle is secured in its extended position, to a second position wherein the needle is not secured in its extended position, and a needle retraction means for biasing the needle toward a position within the housing, whereby when the needle is not secured in

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its extended position, the needle is retracted to its housing position, wherein the injection end of the needle is positioned within the housing; and the engaging member can not be biased to its second position unless the needle is at its housing position, thereby preventing the injection end of the needle from being extended beyond the base portion of the housing when the separable base is removed from the housing.

16. However, Hunn et al. teaches the means for separably affixing comprises engagements 1a (fig. 11-12) in the opposed surface of the separable base; and engaging members 6c (fig. 11-12) extending from the base portion of the housing; wherein the engaging members have a first position associated with the engagement wherein the removable base is secured to the housing (see fig. 11), and a second position associated with the engagement wherein the removable base is not secured to the housing (see fig. 12); the removable base has a slot in the opposed surface, wherein the engaging member has a latch whereby the latch engages the slot in its first position (see fig. 11 and 12; element 6c is formed as a latch that engages a slot in element 1a), thereby securing the separable base to the housing (shown in fig. 11), and wherein the engaging member can be biased to the second position wherein the latch is not engaged with the slot, thereby unsecuring the separable base to the housing (par. 0067; fig. 11-12); the engaging member has a button 6b (fig. 11-12) affixed thereto configured to accept a biasing force from outside the housing (par. 0067, fig. 11-12), which biases the latch of the engaging member to its second, unsecured position (par. 0067; fig. 11-12); a means for retracting (comprising elements 22, 23, and 25, fig. 10-12) the injection needle whereby the injection end of the needle is retracted from its



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extended position (shown in fig. 10) to a position within the housing (shown in fig. 11-12); the retracting means comprises a means 25 (fig. 10-12) for moving a needle insertion securement 23 (fig. 10-12) from a first position wherein the needle is secured in its extended position, to a second position wherein the needle is not secured in its extended position (par. 0074), and a needle retraction means 22 (fig. 10-12) for biasing the needle toward a position within the housing, whereby when the needle is not secured in its extended position, the needle is retracted to its housing position, wherein the injection end of the needle is positioned within the housing (see fig. 10-12); and the engaging member (as best understood, the engaging member referred to by applicant here is assumed to be the same as that in claim 6) can not be biased to its second position unless the needle is at its housing position (see fig. 10; depressing 6b when the needle is in this extended position would not be possible because of the presence of element 27 between the tabs 6b), thereby preventing the injection end of the needle from being extended beyond the base portion of the housing when the separable base is removed from the housing (par. 0018).

17. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the McConnell-Montalvo et al. apparatus such that the means for separably affixing comprises engagements in the opposed surface of the separable base; and engaging members extending from the base portion of the housing; wherein the engaging members have a first position associated with the engagement wherein the removable base is secured to the housing, and a second position associated with the engagement wherein the removable base is not secured to

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the housing; the removable base has a slot in the opposed surface, wherein the engaging member has a latch whereby the latch engages the slot in its first position, thereby securing the separable base to the housing, and wherein the engaging member can be biased to the second position wherein the latch is not engaged with the slot, thereby unsecuring the separable base to the housing; the engaging member has a button affixed thereto configured to accept a biasing force from outside the housing (preferably, through an opening within the housing), which biases the latch of the engaging member to its second, unsecured position; a means for retracting the injection needle whereby the injection end of the needle is retracted from its extended position to a position within the housing; the retracting means comprises a means for moving a needle insertion securement from a first position wherein the needle is secured in its extended position, to a second position wherein the needle is not secured in its extended position, and a needle retraction means for biasing the needle toward a position within the housing, whereby when the needle is not secured in its extended position, the needle is retracted to its housing position, wherein the injection end of the needle is positioned within the housing; and the engaging member can not be biased to its second position unless the needle is at its housing position, thereby preventing the injection end of the needle from being extended beyond the base portion of the housing when the separable base is removed from the housing, as taught by Hunn et al., for the purpose of preventing unintentional user injury (par. 0018).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 7:00 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art  
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